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10/559,745

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Takayoshi Mamine

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EXAMINER

YU, MELANIE J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

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01/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/559,745 | Applicant(s) MAMINE ET AL. | |
| | Examiner MELANIE YU | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 21 October 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment to claim 4 requires the following new limitation: "the lower layer is spaced from the upper layer in a thickness direction by *at least* a depth of focus of the fluorescence". This limitation is not taught by the instant specification and is considered new matter. It is noted that page 16 of the instant specification teaches a signal recording film (which is on lower layer) spaced in a thickness direction from the reaction region (which is on the upper layer) from a depth of focus of laser beams to be irradiated in order to excite fluorescence. This part of the instant specification does not teach that the lower layer is spaced from the upper layer at "*at least*" a depth of focus of the fluorescence and also teaches the depth relative to the focus of laser beams, not the depth relative to the focus of fluorescence. Therefore the new limitation is not provided for by the instant specification and is considered new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard, Jr. et al. (US 6,143,247).

Sheppard, Jr. et al. teach a bioassay apparatus for performing bioassay comprising:

a substrate holder for holding and rotationally driving a substrate (platform, col. 10, lines 15-18) for bioassay (col. 5, lines 43-53; col. 13, lines 10-18), the substrate including:

a reaction region formed on an upper layer of the substrate (platform provided with wells that comprise specific binding reagents, specific binding reagents are in the well which is on the upper surface of the substrate and therefore forms an upper layer, col. 10, lines 32-39; col. 8, lines 12-14; reaction region 11 is on upper layer of substrate 14, Fig. 1D), and

an information region formed on a lower layer of the substrate (pits formed onto lower surface of substrate with lower layer of reflective coating, col. 8, lines 11-12; col. 11, lines 53-60; reflective material 15 on substrate 14, Fig. 1D),

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wherein the reaction region is adapted so that a sample material and a fluorescence marking agent are permitted to be dropped from an upper side of the substrate (sample input 21 is facing upper side of the substrate, Fig. 2; col. 12, lines 52-67) and serving as a field of mutual reaction between the probe material and the sample material (reaction region has probe material that reacts with the sample, col. 18, lines 31-65),

and the reaction region receiving fluorescence with respect to the fluorescence marking agent from a lower side of the substrate (light source on bottom side of platform, col. 21, lines 47-56; light source 54 on bottom side of platform 52, Fig. 5D) and the information region receiving light from a lower side of the substrate to record and reproduce information contained in the information region (light source on bottom side of platform, col. 21, lines 47-56; elements for reading information region includes a light and is on bottom side of platform 52, Fig. 5D; col. 14, lines 56-67),

wherein the lower layer is spaced from the upper layer in a thickness direction by at least a depth of focus of the fluorescence (upper layer and reflective lower layer are spaced apart by substrate, col. 11, lines 53-60; reflective material 15 is lower layer, upper layer 11 is reaction region and substrate 14 is the spacer in the thickness direction between the upper and lower layers, Fig. 1D; fluorescent signal is transmitted through the substrate as seen in Fig. 5D and therefore the thickness of the substrate is a thickness that is at least a depth of focus of the fluorescence);

a fluorescence detection optical system for irradiating the fluorescence having a first wavelength with respect to the reaction region of the substrate to detect the

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fluorescence having the first wavelength produced from the fluorescence marking agent in accordance with the fluorescence (col. 14, lines 31-55; fluorescent markers are detected, col. 22, lines 48-67; col. 32, lines 52-67; fluorescence and information reading/producing optical system are separate, col. 21, line 57-col. 22, line 47, therefore the fluorescence light system operates at a first wavelength, col.12, lines 15-35); and an information recording/reproducing optical system for irradiating the light having a second wavelength with respect to the information region of the substrate (col. 14, lines 56-67; fluorescence and information reading/producing optical system are separate, col. 21, line 57-col. 22, line 47, and therefore the information recording/reproducing system operates at a second wavelength, col.12, lines 15-35).

With respect to claim 5, Sheppard, Jr. et al. teach the substrate being circular shaped (col. 10, lines 21-25) and the substrate holder rotationally driving the circular shaped substrate (col. 5, lines 43-53).

Response to Arguments

4. Applicant's arguments with respect to claims 3 and 4 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sheppard et al. teaching an upper layer and a lower layer of a substrate separated in a thickness direction by at least a depth of focus of the fluorescence.

Conclusion

5. No claims are allowed.

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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
January 15, 2009